IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* JOHN UNDERWOOD, Plaintiff, v. GENENTECH, INC., et al., Defendants.	CIVIL ACTION No. 03-3983

THE UNITED STATES OF AMERICA'S STATEMENT OF INTEREST IN RESPONSE TO MOTION OF GENENTECH, INC., TO DISMISS RELATOR JOHN UNDERWOOD'S SECOND AMENDED COMPLAINT

The United States, the real party in interest in this action, hereby submits this Statement of Interest pursuant to 28 U.S.C. § 517 to respond to certain arguments raised in Defendant Genentech's Motion to Dismiss the Relator's Second Amended Complaint. The United States remains a real party in interest in this matter, even though it has not intervened in the action. *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 231 (1st Cir. 2004). The False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, is the United States government's primary tool used to redress fraud on the government. As such, the statute should be read broadly to reach all fraudulent attempts to cause the government to pay out sums of money. *United States v. Neifert-White*, 390 U.S. 228, 233 (1968). Thus, the United States has a keen interest in the development of the law in this area and in the correct application of the law in this, and similar, cases.

The United States submits this brief in response to certain of the legal arguments by Genentech, which has misstated the law on several aspects of the False Claims Act. In particular, the United States submits that there are four fundamental tenets of False Claims Act cases that are either obscured or ignored by Genentech's Motion: (1) a claim for payment of services that are not reimbursable by federal health programs constitutes a "false claim" ; (2) a drug manufacturer "causes" a provider to submit a false claim for reimbursement under federal health programs if that false claim was a reasonably foreseeable consequence of the drug manufacturer's conduct; (3) false claims for reimbursement of medical treatment that is not covered by federal health programs are material to the government's payment decisions; and (4) a violation of the Anti-Kickback Statute renders all resulting claims "false" for FCA purposes. The United States takes no position on whether Relator has adequately plead facts that would state a cognizable claim under the FCA as properly interpreted. The United States also takes no position as to whether Relator has sufficiently plead elements of falsity, causation, or materiality, but submits this brief to clarify what the law requires as to these issues.[1]

I. Claims for Payment of Services That Are Not Reimbursable by Federal Health Programs are False as a Matter of Law

Under the FCA, a claim is "false" if, among other things, it seeks payment for treatment that is not statutorily eligible for reimbursement. Medicare covers only reasonable and necessary medical services. 42 U.S.C. § 1395y(a)(1)(A); *see also* 42 U.S.C. § 1320c-5(a)(1) (requiring that

[1] The United States does request that should the Court decide to dismiss Relator's Second Amended Complaint for failure to plead fraud with particularity, the dismissal should be without prejudice as to the United States. *See United States ex rel. Williams v. Bell Helicopter Textron Inc.*, 417 F.3d 450, 455 (5th Cir. 2005).

the services provided be economical medical services, and even then only to the extent medically necessary). Indeed, the Medicare statute contains an express condition that "no payment may be made" for items or services which "are not reasonable and necessary for the diagnosis and treatment of illness or injury." 42 U.S.C. § 1395y(a); 42 C.F.R. § 411.15(k)(1); *see also Heckler v. Ringer*, 466 U.S. 602, 605 (1984) (recognizing that this provision "precludes reimbursement for any items or services . . . which are not reasonable and necessary for the diagnosis or treatment of illness or injury"). Medicare's guidance regarding coverage for an off-label use similarly ties coverage to medical necessity. That guidance provides that coverage is only appropriate where the off-label use is "medically accepted," taking into account certain drug compendia (*e.g.*, Drugdex, American Hospital Formulary Service, and U.S. Pharmacopeia-Drug Information), authoritative medical literature, and/or accepted standards of medical practice.[2] *See* Medicare Benefit Policy Manual Ch. 6 § 30 & Ch. 15, §§ 40.4.1 & .2.

Courts have held that when a healthcare provider prescribes a drug for a use that is not covered by federal programs such as Medicare or Medicaid, the provider's claim for reimbursement of that prescription is "false" under the FCA. *See United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 51-53 (D. Mass. 2001) ("*Parke-Davis I*") ("The alleged FCA violation arises - not from unlawful off-label marketing activity itself - but from the submission of Medicaid claims for uncovered off-label uses induced by Defendant's fraudulent conduct."); *United States ex rel Strom v. Scios*, 2009 WL 5062323, at *7-8 (N.D. Cal. Dec. 23, 2009) ("Because the [Medicare] statute permits reimbursement only for 'reasonable and necessary' treatments, [an off-label prescription] in a context where it is not 'reasonable' or 'necessary' would be statutorily ineligible for reimbursement. This satisfies the FCA's requirement of a 'false' statement."); *see also Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975) (finding that submission of claims for services not covered by Medicare violated the FCA). This rule is consistent with a host of other situations in which courts have found FCA liability despite there being nothing false on the face of the claims in question. *See United States ex rel. Marcus v. Hess*, 317 U.S. 537, 543-44 (1943) (bid rigging to obtain a contract renders the claims submitted under the fraudulently procured contract false); *United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008) (claim may be ineligible for payment where physician received a kickback for the billed service); *United States v. Kensington Hosp.*, 760 F. Supp. 1120, 1127-28 (E.D. Pa. 1991) ("payment for services not medically necessary clearly constitutes an injury to the government sufficient to withstand a motion to dismiss"). Thus, Genentech's analysis under "certification theory" is simply inapposite with respect to off-label usage that is not otherwise covered by federal health programs. Whether the provider "certified" on the claim for payment that the prescribed usage was "on-label" or otherwise reimbursable is irrelevant. Rather, the core question for "falsity" under the FCA is whether the government received a bill from a healthcare provider for an item or service that was not legally reimbursable.

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[2] The Medicaid statute contains similar provisions for coverage of prescription drugs. Medicaid defines a "covered outpatient drug" as a drug dispensed by prescription and approved as safe and effective under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 355 & 357, but does not include drugs "used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(2). "Medically accepted indication" is defined as including "any use for a covered outpatient drug which is approved under the FDCA," or "which is supported by one or more citations included or approved for inclusion in any of the [three compendia listed above]." *Id.* at § 1396r-8(k)(6).

Genentech's analysis also misstates the law to the extent that it implies that Relator needs to allege that the Defendant both made a false statement *and* submitted a false claim. The argument conflates the first two sections of the FCA, which provide independent and distinct bases for FCA liability. *Compare* 31 U.S.C. § 3729(a)(1) *with* (a)(2).[3] Liability under Section 3729(a)(1) does not require proof that a defendant made a false statement; it requires only proof that the defendant presented or caused the presentment of a false claim. *See United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731-33 (1st Cir. 2007) (separately analyzing false statement allegations under Section 3729(a)(2)). For this reason, the case cited by Genentech, *United States ex rel. Hess v. Sanofi-Synthelabo, Inc.*, 2006 WL 1064127, at *7 (E.D. Mo. Apr. 21, 2006), was wrongly decided because it failed to consider liability under Section (a)(1), which does not require proof of any false statement at all.

Furthermore, contrary to what defendants' brief implies, for a statement to be "false," it need not be an affirmative misrepresentation; a material omission will suffice: "[H]alf the truth may obviously amount to a lie, if it is understood to be the whole." *W. Page Keeton, Prosser & Keeton on the Law of Torts* § 106, at 738 (5th ed. 1984); *see Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 732 (7th Cir. 1999) (observing that a half-truth may amount to a false statement under the FCA in certain circumstances); *United States ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 199 (D.C. Cir. 1995) (finding that false progress reports may constitute false statements under the FCA); *United States ex rel. Fry v. Guidant Corp.*, 2006 WL 2633740, at *10-11 (M.D. Tenn. Sept. 3, 2006) (finding representation was rendered false by concealment of material information); *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 43 (D. Mass. 2000) (an "omitted material fact," such as the existence of illegal kickbacks, may be actionable under the FCA). Thus, a statement urging a physician to prescribe a drug for an unapproved, off-label use could well amount to a half-truth and satisfy the false statement requirement of section (a)(2), where, for example, the drug sales representative fails to mention that the evidence does not support the drug's efficacy for the use he or she is promoting or the FDA has specifically concluded that the drug is not safe or effective for that use.

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[3] The FCA was recently amended and these sections were recodified as 31 U.S.C. §§ 3729(a)(1)(A) & (a)(1)(B).

II. Conduct That Foreseeably Causes the Filing of False Claims Violates the False Claims Act

Relator's Second Amended Complaint alleges that the Defendant *caused* false claims to be submitted to Medicare and Medicaid for prescriptions for off-label uses of Rituxan. In determining whether a manufacturer may be liable for causing submission of false claims based on off-label marketing conduct, courts analyze causation based on general tort law principles. *See United States ex rel. Cantekin v. Univ. of Pittsburgh*, 192 F.3d 402, 415 (3d Cir. 1999) (discussing principles of causation); *Parke-Davis II*, 2003 WL 22048255 at *4-6. In *Parke-Davis II*, the court found that causation is satisfied where (a) the drug manufacturer's alleged off-label marketing was a "substantial factor" in producing the false claims and (b) it was "foreseeable" that the off-label marketing would result in false claims. 2003 WL 22048255 at *4-6. That court, like others presented with FCA cases based on allegations of off-label marketing, also found that the actions of healthcare providers are not an intervening force that breaks the chain of legal causation, particularly because influencing those actions is the goal of off-label promotion. *Id.* at *5 ("[T]he participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud."); *see also Scios*, 2009 WL 5062323 at *7 (denying a motion to dismiss and agreeing with the *Parke-Davis* court that the independent actions of physicians "only breaks the causal connection when it is unforeseeable" that a particular drug would be billed to a federal health care program). Indeed, the pharmaceutical industry would not employ the army of sales representatives who promote their products if these sales efforts had no effect on physician practices. Thus, Genentech is wrong to suggest that the "independent medical judgment" of physicians cuts off the causal chain for purposes of FCA liability based on off-label promotion. Genentech similarly misconstrues the causation standard of foreseeability in suggesting that Relator must "distinguish" the foreseeable consequence of a physician submitting an off-label reimbursement claim based on his independent judgment from the foreseeable consequence that the claim was based on the company's off-label promotion. The question is not whether separate and apart from the defendant's conduct some false claim may still have been submitted. The relevant question is only whether it was foreseeable that Genentech's conduct would result in some false claims being submitted.

III. The Fact That a Claim Is For an Off-Label, Non-Reimbursable Use Is Material to the Government's Decision to Pay That Claim

Genentech also suggests that a claim for payment of a non-reimbursable, off-label drug prescription cannot be material if the government doesn't ask for information that would reveal that the claim is not covered by Medicare or Medicaid. The Third Circuit has found that the materiality requirement may be satisfied if a reasonable person would know that the government agency would consider the information in question important to its payment decision. *Cantekin*, 192 F.3d at 416. Other courts have defined materiality similarly, stating that a false claim is material if it "has a natural tendency to influence agency action or is capable of influencing agency action." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999).[4]

As an initial matter, Genentech's argument ignores the multiple statutory and regulatory provisions (discussed in Section I, *supra*) that demonstrate that the government will not pay for certain off-label uses of a drug. Since these statutes provide that CMS may not pay a claim for a non-covered off-label prescription, the submission of such a claim is material to the government's payment decision. Genentech claims that "there is no law authorizing the Government to withhold payment from physicians based on the conduct of drug manufacturers." Def. Br. at 21. However, the Medicare statute makes plain that no payment shall be made for services that the Secretary has determined are not reasonable and necessary, as discussed above.

Moreover, Genentech's argument attempts to eviscerate the courts' long-standing recognition that those who deal with the Government must "turn square corners" and cannot take advantage of government officials who may have too few resources to catch attempted fraud at its inception. *See, e.g., Rock Island, Arkansas & Louisiana R.R. v. United States*, 254 U.S. 141, 143 (1920); *Rogan*, 517 F.3d at 452 ("The United States is entitled to guard the public fisc against schemes designed to take advantage of overworked, harried, or inattentive disbursing officers."). The Government processes millions of claims for payment by federal health programs each year, and requiring it, as Genentech apparently suggests, to examine every claim it pays for potential underlying misconduct is patently unreasonable. *See id.*

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[4] The FCA has also been recently amended to expressly define "materiality" in this fashion. *See* 31 U.S.C. § 3729(b)(4) (2009) (defining "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property").

Genentech also argues that Relator's Second Amended Complaint fails because he does not allege that the Defendant's unlawful off-label promotion itself was material to the government's reimbursement decisions. However, as noted, "[m]ateriality depends on whether *the false statement* has a natural tendency to influence agency action or is capable of influencing agency action." *Harrison*, 176 F.3d at 785 (emphasis added). As noted above, a half-truth may amount to a false statement, for example, if the evidence does not support the drug's efficacy for the use a sales rep is promoting or the FDA has specifically concluded that the drug is not safe or effective for that use.

Finally, Genentech's First Amendment arguments are inapposite to the extent that Relator alleges that the Defendant engaged in false and misleading speech, which is not constitutionally protected. Those arguments are also not relevant to the extent that the falsity of the claims at issue here turn not on the Defendant's speech but on the fact that the federal health programs did not cover Rituxan for certain off-label uses during the time period at issue. And to the extent that Genentech is arguing that the government authorized payment of Rituxan claims, that is clearly not an issue that can be resolved at the Motion to Dismiss stage.

IV. Violations of the Anti-Kickback Statute Render Any Resulting Claims For Payment False

Genentech also misstates the law in suggesting that a violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS"), does not render any resulting claims for payment false. Contrary to Genentech's arguments, FCA liability can be based on a violation of the AKS for two separate and distinct reasons: (1) claims seeking payment for services tainted by kickbacks are "factually false" because compliance with the AKS is a condition of payment; and

(2) health care providers must certify in their provider enrollment agreement that they will comply with the AKS as a condition of payment.

A. Compliance with the AKS is a condition of payment and thus any claims for payment tainted by kickbacks are "factually false"

Although a claim may plainly be "false" under the FCA where it rests upon a false certification of compliance with a condition of payment (express or implied), it is not necessary to examine any "certifications" made in connection with claims for goods or services that do not conform to the government's stated criteria for payment. In such circumstances, the presentation of a claim is "factually false" regardless of what "certifications" are made in conjunction with such a claim. Thus, because the AKS expressly prohibits the government from paying for services tainted by kickbacks, a claim seeking payment for such services is "factually false" (*i.e.*, the services are not what the government bargained for), and the FCA imposes liability where a defendant knowingly "causes" such a claim to be presented.

It is well established that compliance with the AKS is a condition of payment under the Medicare and Medicaid programs. *See Rogan*, 517 F.3d at 452-53; *United States ex rel. McNutt v. Haleyville Medical Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005); *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d 12, 18 (D. Mass. 2007) ("*AWP Litigation*") ("compliance with the anti-kickback statute is a prerequisite to payment in the Medicare program"); *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 616 (N.D. Ill. 2003) ("Compliance with the AKS is thus central to the reimbursement plan of Medicare."). The government is not required to pay for services tainted by kickbacks because in such circumstances the government has no assurance that the services were provided in the best interest of the patient rather than the financial interests of the health care provider. Thus, a claim for payment of a drug prescription or other medical treatment tainted by kickbacks is factually false in the same way that a claim for payment is false where the defendant delivers a defective product or goods whose price is inflated by the fraudulent conduct of a subcontractor. *See United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) (holding subcontractor liable under FCA where its bid-rigging scheme caused contractor to present inflated claims to government); *United States v. Bornstein*, 423 U.S. 303 (1976) (holding that claims submitted by an innocent prime contractor were "false" within the meaning of the FCA due to fraudulent acts of subcontractor). This is true even if the person submitting the claim to the government makes no express false statements and even if he is unaware of the underlying falsity of his claim. *See United States v. Rivera*, 55 F.3d 703, 707 (1st Cir. 1995) (the FCA reaches fraud where innocent person presents claims for payment to the government); *Mason v. Medline Indus., Inc.*, 2010 WL 653542, at *7 (N.D. Ill. Feb. 18, 2010) ("It is well-established that a person may submit a false claim to the government without knowing it is false.").

The AKS was recently amended to clarify that all claims resulting from illegal kickbacks are false claims within the meaning of the FCA. The Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, § 6402(f)(1) (2010), confirms that an underlying violation of the AKS renders a subsequent claim false. Specifically, the AKS now provides that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]." *See* PPACA § 6402(f), codified at 42 U.S.C. § 1320a-7b(g). The amendment thus clarifies that all claims for services that were tainted by the payment of a kickback are false claims within the meaning of the FCA, regardless of what entity ultimately submitted the claims for payment. As the Supreme Court has observed, such subsequent legislation is helpful in construing the meaning of an earlier statutory provision. *Loving v. United States*, 517 U.S. 748, 770 (1996); *see also Bates v. United States*, 522 U.S. 23, 32 (1997) (rejecting argument that clarifying amendments demonstrated that prior version of statute did not cover the conduct in question). Thus, there should now be no doubt that a claim resulting from an illegal kickback is a false claim under the FCA, regardless of what "certifications" are made by the person submitting the claim.

B. A violation of the AKS also grounds FCA liability under a "certification theory"

Because claims tainted by kickbacks are "false" within the meaning of the FCA, and because the statute plainly prohibits not merely the direct submission of false claims to the government but also "causing" the submission of false claims, *see* 31 U.S.C. §§ 3729 (a)(1), the court need not consider whether the Second Amended Complaint stated a claim under either an express or implied certification theory of liability. However, if the court does choose to reach that issue, a violation of the AKS can still be grounds for FCA liability under implied certification theory.

Numerous courts have held that claims resulting from illegal kickbacks are false claims under an "implied certification" theory. *See, e.g., AWP Litigation*, 491 F. Supp. 2d at 17; *McNutt*, 423 F.3d at 1259-60; *United States ex rel. Jamison v. McKesson Corp.*, 2009 WL 3176168, at *11-12 (N.D. Miss. 2009); *United States ex rel. Pogue v. Diabetic Treatment Centers of Am., et al.*, 565 F. Supp. 2d 153, 158-59 (D.D.C. 2008) ("*Pogue II*"); *United States ex rel. Bartless v. Tyrone Hosp, Inc.*, 234 F.R.D. 113, 121 (W.D. Pa. 2006); *United States v. Rogan*, 459 F. Supp. 2d 692, 718 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008); *Parke-Davis II*, 2003 WL 22048255, at *7; *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 615 (N.D. Ill. 2003); *United States ex rel. Barrett v. Columbia/HCA Healthcare*, 251 F. Supp. 2d 28, 32-34 (D.D.C. 2003); *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 238 F. Supp. 2d 258, 264 (D.D.C. 2002) ("*Pogue I*"); *United States ex rel. Kneepkins v. Gambro Healthcare*, 115 F. Supp. 2d 35, 43 (D. Mass. 2000). "To state otherwise would be to allow participation and reimbursement for supplies purchased illegally only because the claimant had the luck of not being caught and convicted in the first place. Reimbursing the claimant for the supplies would put the government in the position of funding illegal kickbacks after the fact." *Bidani*, 264 F. Supp. 2d at 615. The rationale of such cases is that the FCA is a remedial statute that should be read broadly and compliance with the AKS is a condition of payment under the Medicare program. *See AWP Litigation*, 491 F. Supp. 2d at 17.

Genentech cites the courts' decisions in *Rodriguez v. Our Lady of Lourdes Med. Ctr.*, 552 F.3d 297 (3d Cir. 2008) and *United States ex rel. Westmoreland v. Amgen, et al.*, 2010 WL 1634315 (D. Mass. Apr. 23, 2010) in support of its argument that implied certification theory cannot "transform a violation of the AKS into an actionable predicate for a FCA claim." Def. Br. at 24. Notably, the *Westmoreland* decision acknowledged that the theory of implied certification is viable as a basis for establishing FCA liability.[5] In discussing implied certification, both *Rodriguez* and *Westmoreland* relied on *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 699-700 (2d Cir. 2001), for the proposition that to succeed under this theory, "it is necessary to allege not only a receipt of federal funds and a failure to comply with applicable regulations, but also that payment of the federal funds was in some way conditioned on compliance with those regulations." *Rodriguez*, 552 F.3d at 304 (citing *Mikes*, 274 F.3d at 697); *see also Westmoreland*, 2010 WL 1634315 at *11. As Genentech also observes, the court in *Westmoreland* found that implied certification liability could not be predicated on a violation of the AKS, despite acknowledging that the AKS is a condition of payment. *Id.* The *Westmoreland* court reasoned that "[w]here courts constructively impose scienter based on a defendant's submission of a claim, adequate notice should be given that compliance is a precondition to payment by an express statement in the relevant statute or regulation." *Id.*

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[5] In *Rodriguez*, the Third Circuit declined to expressly adopt false certification theory as grounds for FCA liability, but nevertheless discussed implied certification theory and assumed application for purposes of disposing of the case before it, which did not involve the AKS. 552 F.3d at 304-05.

There are two fundamental problems with the *Westmoreland* rationale, however. First, even under the *Mikes* standard, the express language of the AKS combined with the Medicare provider enrollment agreement and the Medicare claim form provide more than a sufficient basis on which to find an express statement that compliance with the AKS is a condition of payment.[6] As noted above, however, the AKS does link the illegal kickbacks with the payment of claims by federal health care programs, because it expressly links the illegal kickback to an item or service for which payment may be made under a federal health program. As noted above, the AKS was amended to make clear that all claims resulting from illegal kickbacks are "false" under the FCA. That the AKS is a condition of payment is further supported by the Medicare provider enrollment agreement that states that "payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with . . . the [AKS]." CMS Forms 855a, at 37 and 855b, at 30

[6] Notably, *Mikes* was not a case predicated on an underlying violation of the AKS. Rather, the case concerned whether a violation of a quality of care standard could amount to liability under the FCA.

(available at https://www.cms.gov/cmsforms/downloads/cms855a.pdf and https://www.cms.gov/cmsforms/downloads/cms855b.pdf) (copies attached). Moreover, the claim form itself that is submitted to seek payment from the Medicare program contains a certification of compliance with all applicable laws. Even under the *Mikes* standard, these statements taken together are more than enough to satisfy the requirement of an express statement that claims that result from illegal kickbacks are not eligible for payment by Medicare. Indeed, one court has held that the provider enrollment agreement alone "comports with even the most parsimonious application of the implied certification theory" as espoused by *Mikes*. *Pogue II*, 565 F. Supp. 2d at 159.

Second, the *Westmoreland* standard also conflates the concepts of falsity and scienter. The question of whether a claim is false depends only on whether the claim was eligible for payment in light of applicable law. *See United States ex rel. Oliver v. The Parsons Co.*, 195 F.3d 457, 463 (9th Cir. 2000). By limiting the implied certification liability to those instances in which the particular statutory provision expressly states that compliance is a condition of payment, the *Westmoreland* standard erroneously restricts a finding of *falsity* to those instances in which the defendant is *on notice* that it failed to comply with the prerequisite to payment. However, any concern about an unwitting defendant being subject to FCA liability is adequately and appropriately addressed under the FCA's separate knowledge requirement. *See United States ex rel. Augustine v. Century Health Servs.*, 289 F.3d 409, 416 (6th Cir. 2002); *United States ex rel. Shaw v. AAA Engineering*, 213 F.3d 519, 533 (10th Cir. 2000). Furthermore, the practical effect of the *Westmoreland* decision is that there may be a bounty of evidence demonstrating that a drug company *knows* that claims resulting from illegal kickbacks are not eligible for payment and *knows* that a doctor to whom kickbacks were paid submitted (or caused to be submitted) claims to federal health programs, yet the drug company may nonetheless escape liability under the FCA because the AKS does not "expressly" state that such claims are not payable. The rigidity of this analysis should be rejected in favor of an interpretation that furthers, not frustrates, the remedial goals of the FCA.

Finally, the United States takes no position as to whether Relator has sufficiently pled underlying kickbacks here. However, the United States submits that Defendant is incorrect in suggesting that such a pleading requires that a plaintiff allege that a defendant does not fall within a safe harbor. *See United States v. Shaw*, 106 F. Supp. 2d 103 (D. Mass. 2000) (plaintiff not required to allege that defendant's conduct did not fall within AKS "safe harbor").

Respectfully submitted,

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Dated: July 6, 2010

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing **THE UNITED STATES OF AMERICA'S STATEMENT OF INTEREST IN RESPONSE TO MOTION OF GENENTECH, INC., TO DISMISS RELATOR JOHN UNDERWOOD'S SECOND AMENDED COMPLAINT** was sent by First Class United States Mail, postage prepaid, this 6th day of July, 2010, to the following:

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